United States Court of Appeals

for the Second Circuit

APPELLANT'S REPLY BRIEF

74-2477

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

B

P/S

STERLING DRUG INC., WINTHROP PRODUCTS, INC. and BREON LABORATORIES, INC.,

Plaintiffs-Appellants,

- against -

CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare, and ALEXANDER M. SCHMIDT, Commissioner of Foor and Drugs,

Defendants-Appellees.

REPLY BRIEF OF PLAINTIFFS-APPELLANTS

ROGERS HOGE & HILLS
Attorneys for Plaintiffs-Appellants
90 Park Avenue
New York, New York 10016

Of Counsel:

WILLIAM F. WEIGEL
JAMES B. SWIRE
E. CARRINGTON BOGGAN

JAMES H. LUTHER
ROGER M. RODWIN
Sterling Drug Inc.

3

TABLE OF CONTENTS

TABLE OF CASES

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

Docket No. 74-2477

STERLING DRUG INC., WINTHROP PRODUCTS, INC. and BREON LABORATORIES, INC.,

Plaintiffs-Appellants,

- against -

CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare, and Alexander M. Schmidt, Commissioner of Food and Drugs,

Defendants-Appellees.

REPLY BRIEF OF PLAINTIFFS-APPELLANTS

ARGUMENT

POINT I

THE CASES ON EXCEPTIONS TO THE EXHAUSTION DOCTRINE SUPPORT APPELLANTS HERE

The government's brief fails to perceive that the general development of the law in recent years has been away

from the earlier rigid following of the exhaustion doctrine when judicial intervention is found necessary to prevent a party from being subjected to arbitrary or otherwise unlawful agency action. Just as the high judicial hopes for competent, fair, expeditious, and expert administrative action led to the formulation of the exhaustion doctrine in the first instance, increasing judicial experience over the years with agency action that is none of these, but, rather, is sometimes arbitrary, contrary to law, extremely unexpeditious, and astonishingly lacking in the application of the agency's supposed expertise, has led the courts to fashion a variety of exceptions to the exhaustion doctrine to relieve affected parties of the deprivation of basic fairness that would result were they to rigidly adhere to the exhaustion doctrine in the face of this latter and, unfortunately, increasingly common, type of agency action.

Nonetheless, the government, in its attempt to find some grounds for permitting the FDA to proceed here pursuant to its unbelievably confused, inconsistent, and unlawful Notice, consistently relies for its authority on cases long since eroded by the development of the law described above. Its strained attempts to distinguish the current controlling case law on exhaustion demonstrate its failure to correctly understand the law's evolution.

The argument of the government in this case is remarkably similar to that of the Federal Trade Commission in California ex rel. Christensen v. Federal Trade Commission, _____ F. Supp. _____ (Docket No. C-74-1927, RHS, N.S. Cal., Decided October 29, 1974), (BNA Antitrust & Trade Reg. Rept. No. 688, Nov. 12, 1974, p. 12),which when faced with a motion for a preliminary injunction on the grounds that an FTC proceeding against the California Milk Producer's Advisory Board was without jurisdiction, argued that a federal court should not exert its jurisdiction over the dispute until the California respondents "have exhausted their administrative remedies before the Commission." In rejecting this argument, the district court there held that

> "The exception to the exhaustion requirement recognized in Leedom v. Kyne, 358 U.S. 184, 188-189 (1958), is fully applicable here, since the Commission is apparently exceeding its jurisdiction...[and] the issue appears to be a simple question of statutory interpretation which does not require agency expertise in making factual determinations." Id.

Defendants' tortured attempts to find succor in S.E.C. v. Otis & Co., 338 U.S. 843 (1949); Coca-Cola Company v. F.T.C., 475 F.2d 299 (5th Cir. 1973), cert. denied 414 U.S. 877 (1973);

and Petro v. Bakely, 353 F.2d 511 (3d Cir. 1965) are unavailing. In Otis, the determination upon which the res judicata argument was based arose from an SEC investigatory hearing, in which the SEC sought to compel disclosure of material alleged to be covered by the attorney-client privilege. The determination was not one which followed a formal agency adjudicatory proceeding, as is the case here.

The Supreme Court decision reversing the District of Columbia Circuit's decision that res judicata barred a formal SEC proceeding pursuant to a complaint is thus understandable. The new SEC proceeding was the first agency adjudicatory proceeding to be instituted in the matter, whereas with Alevaire, there has already been one adjudicatory proceeding on the issue of comparing Alevaire with its vehicle, which concluded in plaintiffs' favor with this Court's decision confirming FDA's abandonment of that issue.

Thus the Supreme Court's per curiam reversal in Otis, without opinion, cannot be taken as standing for the broad principle on res judicata enunciated by the Court of Appeals for the Fifth Circuit in Coca-Cola Company v. FTC, supra. Further, as pointed out in our main brief, the issue of res judicata was not even directly at issue in Coca-Cola, but only raised as a hypothetical possibility. Thus, the Supreme Court's per curiam decision in Otis, on its face, stands for no more than a simple holding that

exhaustion was desirable in that case since there had been no prior adjudicatory proceeding, since the cases cited in the per curiam reversal have nothing to do with res judicata. The significant point, however, is that a per curiam decision in an older case contextually much different than the present one and citing as its basis simple exhaustion doctrine authority should not preclude this Court from examining fundamental claims of unfairness in permitting the government to proceed on a previously raised and abandoned theory asserted here, given the extensive background of the government's inequitable prior conduct in this matter, already found by this Court in its prior decision to have been arbitrary.

Even as an exhaustion case, Otis has been seriously undermined by subsequent decisions in cases such as the present one where substantial questions are also raised as to an agency's proceeding in violation of a statute. Otis relied upon Myers v. Bethlehem Steel, 303 U.S. 41 (1938), which is also relied on by the government. However, while Myers, a 1938 case, refused to enjoin the NLRB, Leedom v. Kyne 388 U.S. 184 (1958) subsequently held that injunctions against the NLRB are permissible where "a plain contravention of a statutory mandate" is at issue.

Leedom has been increasingly followed and used to check illegal agency action, not only in NLRB cases, such as Boire v. Miami Herald Publishing Co., 343 F.2d 14, 24 (5th Cir. 1965); but also with respect to other agencies, Federal Trade Commission v. J. Weingarten Inc., 336 F.2d 867 (5th Cir. 1964).

It has also been held in these cases that the propriety of the district court's granting of an injunction does not depend, as the government's brief would suggest, upon whether the statutory provision alleged to have been violated requires action to be taken or to be forborne by the agency, Templeton v. Dixie Color Printing Co., 444 F.2d 1064 (5th Cir. 1971).

Contrary to the government's assertions, there is clearly no agency expertise on either the res judicata or "new information" points which would benefit this Court in deciding the merits of the claims here raised. As to res judicata, it is the res judicata effect of this Court's prior decision which, in relevant part, was based on and confirmed the FDA's abandonment of its prior theory concerning the proper control against which to test Alevaire as a single-entity drug, that is in issue here. Thus this Court, and not the Agency, is clearly the proper authority to pass on that issue, and the FDA has no relevant "legal expertise" on that issue, as claimed by the government (Gov. Brief p. 33).

Similarly, on the "new information" issue, it is simply a legal issue of whether the only information upon which the government claims to be relying - old labeling of the drug and the NAS-NRC report upon which the prior proceedings were based and which clearly on its face classifies Alevaire as a single entity drug - can possibly constitute the "new information" concededly required by the statute to support the new proceeding. Permitting the Agency to to forward would not shed one bit of additional light on these two issues which would assist this Court in reviewing them in conjunction with a review of a final Agency order - particularly since it is already clear what the Agency's position on them is. On the other hand, denying review at this time would subject appellants to serious and irreparable inequities should their claims be ultimately upheld.

It should also be pointed out here that, contrary to the government's misconstruction of appellants' claim, it is not simply the harm of having to go to the expense of another agency proceeding claimed to be illegal that appellants contend would constitute irreparable harm here. It is the continued and undenied destruction of appellants' property right in the drug itself that constitutes the irreparable harm to appellants' here. If compelled to submit to the pending illegal agency proceedings,

the probability is great that appellants will have no viable property right left at the end of such proceedings (A 67). It is this harm - which would also, of course, deprive the public of a useful drug, should appellants ultimately be shown to have been correct in their claims, Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 639, n.2 (1973) (Powell, Justice, concurring), - and not the mere time and expense of relitigation, that constitutes the irreparable harm here and tips the equities overwhelmingly in favor of a determination at the outset of the legality of the government's proposed new proceeding. This conclusion is strongly reinforced by an examination of the Agency's past conduct with respect to Alevaire, which this court has held to have been arbitrary.

The Court below and the government erroneously attempt to rely on the review provisions of the Food Drug and Cosmetic Act, 21 U.S.C. §355(h), as precluding this action, quoting the language of the statute that

> "No objection to the order of the Secretary shall be considered by the Court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure to do so."

This provision, of course, on its face pertains only to actions to review an order of the Secretary. This action, being one which challenges at the outset the legality of the Secretary's proposed action, and not one seeking review of a final order of the Secretary, is clearly not barred by that provision of the statute, but is properly maintainable under the Administrative Procedure Act and the Declaratory Judgment Act, as the Supreme Court has held. Abbot Laboratories v. Gardner, 387 U.S. 136 (1967); Toilet Goods Association v. Gardner, 387 U.S. 158 (1967); Gardner v. Toilet Goods Association, 387 U.S. 167 (1967).

The government's attempts to distinguish Jewel Companies Inc. v. FTC, 432 F.2d 1155 (7th Cir. 1970), and Elmo Division of Drive-X Company v. Dixon, 348 F.2d 342 (D.C. Cir. 1965) points up instead the applicability of those cases where, as here, straightforward questions of statutory construction - i.e., what is "new information" - are involved, Jewel; and where District Court jurisdiction is appellant's only effective remedy to prevent destruction of its constitutionally protected property right, Elmo Division. This Court's decision in Diapulse Corporation v. Commissioner, FDA, 500 F.2d 75 (2d Cir. 1974), also supports a determination by the Court at this time.

The cases cited by the government in which injunctive relief was denied are simply not pertinent to the issues here. In Vaca v. Sipes, 386 U.S. 171 (1967), the issue was not exhaustion at all, but whether the NLRB exclusive jurisdiction over unfair labor practices preempted state court jurisdiction over an action against a union for breach of the duty of fair representation. In Sampson v. Murray, 415 U.S. 61 (1973) and Renegotiation Board v. Bannercraft Co., 415 U.S. 1 (1973), injunctive relief was denied because the only question of irreparable harm raised was that of the time and expense that would be required to exhaust administrative remedies - clearly not the level of harm here involved, which is the continuing destruction of appellants' property in their drug itself. Similarly, in Frito Lay Inc. v. FTC, 380 F.2d 8 (5th Cir. 1967), the only potential injury was the normal cost of litigation, and the alleged procedural irregularities would not have made any possible agency order necessarily invalid, as the illegality of the entire proposal here could result only in an invalid order. And clearly, appellants' claim of deprivation of their property right by its continued virtual destruction in a proceeding violative of due process by virtue of its illegality on two grounds is not a constitutional claim lacking in specificity or stated only in conclusory terms, as the government attempts to argue to bring itself within Bokat v. Tidewater Equipment Co., 363 F.2d 667 (5th Cir. 1966).

Finally, McKart v. United States, 395 U.S. 185 (1969), so heavily relied upon by the government, is totally contrary to the government's position. There, in fact, the government raised the same argument that it raises here: "that failure to require exhaustion in the present case will induce registrants to bypass available administrative remedies." 395 U.S. at 199. The Supreme Court rejected the argument there, as this Court should reject it here, since there was no significant interest to be served by requiring exhaustion where the issues were legal ones primarily within the competence of the courts, not the administrative agency, as the issues here are also. Referring to earlier Supreme Court decisions relied upon by the government, the Court held:

> "Neither those two cases, nor any of the other cases decided by this Court, stand for the proposition that the exhaustion doctrine must be applied blindly in every case." 395 U.S. at 200.

POINT II

THE COURT OF APPEALS FINDINGS BASED ON THE FDA'S MARCH 1973 AND AUGUST 1973 ORDERS AND ON THE AGENCY'S CONCESSIONS MADE BEFORE THIS COURT CONCLUSIVELY ESTABLISH AND CONFIRM THE FDA'S ABANDONMENT OF ITS PRIOR THEORY CONCERNING THE ADEQUACY OF THE CONTROLS USED TO TEST ALEVAIRE, AND BAR THE FDA FROM AGAIN RAISING THAT ISSUE

Defendants contend that even assuming the issue of res judicata, collateral estoppel, and abaondonment can be raised prior to exhaustion of administrative remedies, none of those principles apply here, and the agency is not barred from proceeding. An examination of the background and the context of this court's prior decision will reveal the futility and the self-serving nature of the government's arguments.

The NAS-NRC panel which reviewed Alevaire found there was a lack of evidence that the active ingredient in Alevaire, tyloxapol, was any more effective than water in thinning secretions in the lung. It was in response to this resport, as concurred in by the FDA, that plaintiffs commissioned two new clinical trials to test the precise issue raised by the panel and Agency.

In June 1970, the studies by Drs. Miller and Paez and Cohen were completed and submitted to the FDA. With FDA's advance knowledge, the studies compared Alevaire to water and saline (A 48). These controls were employed because they had been suggested by FDA and because they were logical and proper in that water and saline are commonly used alternatives to Alevaire as mucoevacuant agents. The studies were adequate and well-controlled as defined by FDA's own regulations and they proved Alevaire to be effective as a mucoevacuant and more effective than water and saline.

Plaintiffs did not rest on their own opinion that the Miller-Paez and Cohen studies were adequate and well-controlled. Instead, they submitted those studies to a number of independent experts, "knowledgeable and experienced in the field", (A 41), from some of the leading institutions in America. Each of these experts then made affidavits attesting that the studies were adequate and well-controlled and proved Alevaire to be effective and more effective than water and saline.

In September 1971, the FDA issued a withdrawal order rejecting the Miller-Paez and Cohen studies as allegedly being not adquate and well-controlled. After plaintiffs appealed and filed their brief in the Court of Appeals documenting the fallacious nature of FDA's criticisms, the Agency moved successfully to remand the matter for further consideration.

Over a year later, in March 1973, FDA issued another withdrawal order which raised a new argument that the Miller-Paez and Cohen studies were not well-controlled because the only proper test would be to compare Alevaire against its "inactive" vehicle, i.e., an aqueous solution of sodium bicarbonate and glycerin. 38 Fed. Reg. 6308 (A 23)* Plaintiffs promptly submitted a Petition for Reconsideration thoroughly rebutting this newly raised contention, as well as all others made in the March 1973 order.

Thus, the central issue before the Court of Appeals with regard to the March 1973 withdrawal order was the adequacy and well-controlled nature of the Miller-Paez and Cohen studies, including the adequacy of the control solutions employed in those studies, a point upon which petitioners (appellants here) had submitted extensive evidence in support of the adequacy - and even the desirability (A 62) - of the controls used.

An analysis of this Court's prior decision makes it clear beyond the shadow of a doubt that the Court considered this issue, found that the FDA had conceded its position to be erroneous in this regard, and that the Agency had abandoned its argument and terminated its proceeding insofar as they were based on the proposition that Alevaire had to be tested against its own vehicle.

*Defendants below made the remarkable statement that consistently throughout the proceedings the Agency has demanded that Alevaire be tested against its vehicle (A 138). Yet, the Court of Appeals found that this theory surfaced "for the first time" (A 42) in the March 1973 order and, of course, it was abandoned in the August 1973 order.

In discussing the March 1973 order in its prior decision this Court first referred to the fact that plaintiffs' extensive rebuttal in their Petition for Reconsideration was "apparently well taken." (A 42). The Court addressed the control issue directly, and noted that in the first withdrawal order FDA itself had indicated that "either water or Alevaire minus tyloxapol would be a proper control," (A 42), and further noted, in discussing plaintiffs' Petition for Reconsideration, that it included material "supporting the suitability of controls used in [plaintiffs'] studies." (A 42). The Court's decision then goes on to make it very clear that it considered the effect of issuance of the August 1973 order and the argument before it to be an abandonment of all the grounds previously raised by the defendants. The Court specifically said that "this third order abandoned the grounds on which the prior two orders of March 2nd and August 7th had been based." (A. 43). The Court's decision also specifically quoted defendants' brief, in which defendants' stated that "We confessed error in that order of March 2nd before this Court." (A 44). After six years and three appeals, the attempt

to renew this issue constitutes harassment by defendants which should not be countenanced by this Court. The government attempts to justify such conduct, and asks this court to sanction it, by making the incredible argument that because the Agency itself confessed error and abandoned that issue previously, and because this Court, as a result of that abandonment, found no effective relief it could grant plaintiffs on their appeal from that abandoned March 1973 order and thus dismissed the appeal as moot, the Agency is now free to raise the issue again.

Presumably, under the government's theory, FDA could now come in to this Court on oral argument of this appeal, once more abandon the contention that Alevaire had to be tested against its vehicle, thereby also obtaining a dismissal of this present appeal on that issue as moot, and then raise that issue again at some future time after it succeeded in getting out of its current litigation difficulties! Presumably, the government should be permitted to engage in this tactic ad infinitum, thereby frustrating at its will any effective judicial review of its conduct.

As it happens, however, the present case is not the first instance in which a federal administrative agency has attempted to avoid scrutiny of its actions by such a ploy, and the law is clear that such administrative conduct is not to be sanctioned by the courts. Our instruction on this begins with the Supreme Court's admonition against such agency action in Southern

Pacific Terminal Co. v. I.C.C., 219 U.S. 498, 515 (1911), cited in appellants' main brief. The need for reiteration of the principle is continuingly apparent to this day. In Nader v. Volpe, 475 F.2d 916, 917 (D.C. Cir. 1973), the court, citing Southern Pacific Terminal stated:

> "Consideration of important legal issues 'ought not to be, as they might be, defeated, by short term orders, capable of repetition, yet evading review**'. (Citations omitted)

It is also significant for the present case to note that in Nader v. Volpe, the finding against the government, based upon which the Court refused to refrain from deciding the issue on the grounds of mootness, as urged by the government, arose from admissions by the government itself, as in the present case.

> "In this case, the District Court properly found, on the basis of the Government's own post-hearing memorandum, that temporary exemptions such as the one granted to Checker would be granted to Checker or to other manufacturers in the future, and that to dismiss cases challenging the legality of such exemptions simply because the exemption had been withdrawn or had expired would prevent courts from ever deciding the important question of whether or not the Secretary has authority to issue such exemptions." 475 F.2d at 917

In Moore v. Ogilvie, 394 U.S. 814 (1969), the Supreme Court refused to dismiss as moot a suit brought by independent candidates for the office of elector on the ground asserted by defendants therein that since the election was over, there was no relief which could be granted to the plaintiffs. Notwithstanding the conclusion of the election, the Court found that because the requirements challeged in the suit would recur for future elections, "The problem is therefore 'capable of repetition, yet evading review,' Southern Pacific Terminal Co. v. Interstate Commerce Commission, 219 U.S. 498, 515, 55 L.Ed. 310, 316, 31 S. Ct. 279." Id. at 816. To similar effect is Jeannette Rankin Brigade v. Chief of the Capital Police, 421 F.2d 1090 (D.C. Cir. 1969).

If this Court permits the government to now raise again the previously abandoned issue of whether Alevaire must be tested against its vehicle - the government's abandonment of which induced this Court to dismiss appellants' prior appeal from the order asserting that theory as moot - then the court will be sanctioning the conduct by the Agency constituting the very "repetition evading review" that has been condemned by the Supreme Court and other courts, and will be depriving its own judicial review of FDA orders, as embodied in the Court's May 2, 1974, decision, of finality and effectiveness.

POINT III

THE GOVERNMENT'S BRIEF IN EFFECT ADMITS THAT THE FDA HAS NO "NEW INFORMATION" UPON WHICH TO PROCEED AGAINST ALEVAIRE AS A FIXED COMBINATION DRUG

The government's brief, by clearly specifiying once more the material the FDA purports to rely on as its "new information" to support the "fixed combination" portion of its new proceeding against Alevaire, conclusively establishes the total lack of any material or data which could serve as the statutorily required "new information" to support a proposal against Alevaire on the grounds that it was a "fixed combination" drug and ineffective as such.

The government brief and the August 13, 1974 Federal Register Notice clearly indicate only two items upon which the Agency purports to rely as "new information" to support its "fixed combination" theory: (1) the NAS-NRC report on Alevaire; and (2) certain statements in prior labeling of Alevaire. While the complete inability of either of these to serve as new information for the fixed combination proposal, no matter how much "re-evaluation" they were subjected to by FDA, was fully discussed in appellants' main brief, several points must be made in view of the government's brief.

First. A simple reading of the brief text of the NAS-NRC report itself (A. 59) is enough to dispell any thought that it could serve as a basis for proceeding against Alevaire as a fixed combination drug. The report refers to "this detergent," i.e., tyloxapol, for inhalation, marketed "in a concentration of 0.125%" - again, this is tyloxapol; refers throughout to tyloxapol; and concludes that there is no evidence that the tyloxapol in Alevaire has any effect on secretions in the lung other than that of water.

Thus the NAS-NRC report unambiguously considers Alevaire to be a single-active ingredient product, tyloxapol, in an aqueous vehicle containing sodium bicarbonate and glycerin. The government has in fact conceded that the NAS-NRC report found Alevaire to be a single entity drug, and that the NAS-NRC itself developed the "fixed combination" classification (Gov. Brief p. 64).

Second. The claims from prior labeling of Alevaire cited in the August 13, 1974 notice as indicating that Alevaire is a fixed-combination drug were the same claims submitted with the new drug applications themselves. How can old labeling constitute new information?

Furthermore, that labeling has not even been used by appellants since 1970, and can, therefore, hardly form the basis of a proceeding to withdraw approval of Alevaire's NDA's in 1974.

Third and finally. The misconstruction of Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966) by the government's brief must be rectified. In Bell v. Goddard, the new information relied upon was not merely a re-evaluation of information existing at the time the NDA was approved, as the government would have this Court believe. It was an extensive reevaluation of all clincial experience with the drug, including clincial experience subsequent to the approval of the NDA. In the present case, the FDA is not even relying on a reevaluation of old clincial experience, much less an evaluation of old and new clincial experience. It is not relying on any clinical experience at all, but merely on a rereading of old labeling claims which were before it when the NDA's were first approved, and a NAS-NRC report which does not even conceivably support a fixed combination theory.

We submit that this Court is capable of piercing these transparent fabrications concocted by an agency desperate to avoid, on any theory it might conceivably be able to come up with, the effect of its own prior misconduct in its evaluation of this drug.

POINT IV

THE INJUNCTION PENDING APPEAL SHOULD BE CONTINUED IN EFFECT PENDING DETERMINATION OF THE APPEAL

Should this Court grant appellants the relief prayed, or should it grant any part of that relief, the Court's decision could substantially affect both the form and content of any submission of evidence to the FDA in support of a request for a hearing pursuant to the August 13, 1974 Notice, if in fact any submission pursuant to that Notice would still be required.

Appellants request, therefore, that this Court's injunction pending appeal be continued in effect pending the Court's determination of this appeal, and that submission of any such data to the FDA be in accordance with whatever determination this Court makes on this appeal and within such reasonable time following this Court's determination as the Court may provide

CONCLUSION

For the reasons set forth above and in appellants' main brief, the decision of the District Court should be reversed and the case remanded to the District Court with instructions to enter judgment as prayed in the Complaint.

Respectfully submitted,

ROGERS HOGE & HILLS
Attorneys for Plaintiffs-Appellants

Of Counsel:

Willaim F. Weigel
James B. Swire
E. Carrington Boggan

James H. Luther
Roger M. Rodwin
Sterling Drug Inc.

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

----------x

STERLING DRUG, INC., et al, :

Plaintiffs-Appellants, :

-against- :

CASPAR W. WEINBERGER, :
Secretary of Health, Eduation
and Welfare, et al, :

Defendants-Appellees. :

----------x

AFFIDAVIT OF SERVICE
BY MAIL

Docket No. 74-2477

STATE OF NEW YORK)
: ss.:
COUNTY OF NEW YORK)

THERESA MOCCIA, being duly sworn, deposes and says that she is over 18 years of age and not a party to this action; that she resides at 2264 Ellis Avenue, Bronx, New York 10462; and that she served the Reply Brief of Plaintiffs-Appellants on Defendants-Appellees in this action by mailing a copy thereof, by U.S. Mail, first class, postage paid, to Jerry Seigel, Esq., Assistant United States Attorney, Counsel of record for the Appellees, U.S. Courthouse, Foley Square, New York, New York, this 16th day of December, 1974.

Theresa Moccia
THERESA MOCCIA

Sworn to before me this
16th day of December, 1974.

Anne Santino
Notary Public

ANNE SANTINO
Notary Public, State of New York
No. 41-8761685
Qualified in Queens County
Cert. Filed in New York County
Commission Expires March 30, 1976